one or more divisional or continuation applications directed to the subject matter thereof.

The Examiner rejected claims 27 to 42 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the Examiner objected that the language "a case of disease caused by infection by *B. pertussis*" as used in claims 27 to 39, was unclear. As the Examiner points out, *B. pertussis* is the causative agent of pertussis (whooping cough). It is evident, therefore, that the disease referred to in the claims is that for which the causative agent is *B. pertussis*! There can be no lack of clarity, therefore, in the language adopted.

The Examiner noted claim 40 is drawn to the genus *Bordetella*. It is further noted that claim 40 refers to claim 21, a claim withdrawn from consideration. Claims 40 and 41 consequently have been deleted, rendering the Examiner's objection moot.

The Examiner indicated that the term "selected relative amounts" is vague and fails to adequately circumscribe what is being claimed. The Examiner indicated that the components are either present in a stated ratio (i.e., "relative amounts") or they are not and hence it is unclear what "selected" refers to. However, the Examiner then goes on to state:

> "Although not stated as such in the claims, this terminology would reasonably be interpreted by the artisan to refer to acellular vaccines, and therefore this interpretation is assumed for purposes of this Office Action".

The Examiner, therefore, would appear to have little difficulty in interpreting the language. In this regard, the vaccine requires the presence of PT, FHA, pertactin and agglutinogens of *B. pertussis* in purified form and these components are in relative amounts which are selected to confer protection to the extent of at least about 70% of members of the at-risk population. Thus, a vaccine composition is formulated as a

component (or "acellular" in the Examiner's terminology) vaccine from individual pure components in defined proportions.

Accordingly, it is submitted that the claim language is clear in scope and there is no indefiniteness that requires revision to the claim language.

The Examiner indicated that the term "about" is used consistently in the claims when any numeric parameter is cited. It is noted that it is time honored practice with respect to chemical patent applications to employ the term "about" when defining numerical ranges of parameters, and applicants usage is no different herein. The reason for permitting such practice is an equitable one, so that a would-be infringer cannot escape infringement by employing a value for a parameter which is a scintilla outside a recited numerical range. The claim language, as it has been interpreted by the Court, clearly does not encompass the gross differences suggested by the Examiner and is, in general, considered to include up to about 5% leeway from the recited value. Accordingly, there is no necessity for applicant to modify the claims in this respect for compliance under 35 USC 112, second paragraph.

The Examiner indicated that the term "immunoeffective amount" as used in claim 40 is unclear. While not agreeing with the position taken by the Examiner, claim 40 has been deleted, as discussed above, thereby rendering the objection moot.

The Examiner indicated that the claims address amounts of various components as nitrogen equivalents. The Examiner indicated that it is unclear how the apparent nitrogen equivalent is determined such that the artisan could determine what amounts of the various vaccine components are present. The Examiner states:

> "Because the disclosure provides inadequate guidance with respect to determination of nitrogen values, and in order to expedite prosecution, it is assumed that the amounts of components recited as "nitrogen" are identical to the actual amount of that component".

As to the "inadequate guidance", the Examiner's attention is directed to the specification on page 14, lines 9 to 13, wherein it is stated:

> "... the invention provides vaccines with the following characteristics (µg proteins used herein are based on Kjedahl test results performed on purified concentrates and are expressed as µg of protein nitrogen)..." (emphasis added)

Accordingly, the quantities of proteins used are the quantities expressed as µg of protein nitrogen as determined by the Kjedahl test, a very well known and routine test procedure. Accordingly, there is no indefiniteness in the language adopted, since it is that routinely used to define amounts of proteins. No revisions are required to the claim language in order to comply with the provisions of 35 USC 112, second paragraph.

Having regard to the above discussion and the deletion of claim 40, it is submitted that claims 27 to 42, in so far as they remain in the application are not indefinite and hence the rejection thereof under 35 USC 112, second paragraph, should be withdrawn.

The Examiner indicated that claims 27 to 29, 31 to 34 and 38 to 42 are rejected under 35 USC 102(b) as being clearly anticipated by Englund et al.

The key finding on which the applicants claims are based is the clinical trial results in an at-risk population as described on page 19, line 15 to page 20, line 8 and again on page 43, lines 24 to 31 and Table 4. There is no suggestion in the cited Englund et al reference that the vaccine composition described therein would have an efficacy of at least 70%, as specified in claim 27 and, in particular, the efficacy of at least 80% for the specific case recited in claim 31, in particular about 85% as recited in claim 33, and of at least 70% for the specific case recited in claim 32. There is no possible manner in which such results could be predicted without conducting the clinical trial in question. The rejected claims, therefore, all recite a feature not described in nor obvious from the Englund et al reference and hence claims 27 to 29, 31 to 34 and 38 to 42, in so far as they remain in the application, cannot be considered to be anticipated by Englund et al.

In addition, it is submitted that insufficient information is provided in the Englund et al reference to reproduce the same and hence the disclosure is non-enabling with respect to the formulations described therein and hence is non-anticipatory also for this reason. In particular, it is submitted that the Englund reference contains insufficient detail as to the manner of preparation of the agglutinogens 2 and 3 combination component to enable one skilled in the art to isolate such material.

Accordingly, claims 27 to 29, 31 to 34 and 38 to 42 are not anticipated by Englund et al and hence the rejection thereof as anticipated under 35 USC 102(b) as clearly being anticipated, should be withdrawn.

The Examiner rejected claims 27, 34 and 38 to 42 under 35 USC 102(b) as being clearly anticipated by Cherry.

The NIH/NIAID Swedish trial is referred to in Table 2 of Cherry as being in progress. No details of the various formulations in the third entry are provided and hence there is no enablement of any formulation provided by Table 2. As discussed above with respect to Englund, unless the clinical trial is performed and the results analyzed, it is impossible to predict the degree to which an at-risk population can be protected from the disease caused by *B. pertussis* infection.

Accordingly, each of claims 27, 34 and 38 to 42 is not anticipated by Cherry and hence the rejection of claims 27, 34 and 38 to 42 under 35 USC 102(b) as being anticipated by Cherry should be withdrawn.

The Examiner rejected claims 27 to 42 under 35 USC 103(a) as being unpatentable over Englund et al or Cherry.

As already discussed above, neither Englund et al nor Cherry is enabling of any of applicants various formulations or methods of administration. In addition, it is submitted that the efficiency of the formulations could not have been predicted in advance of clinical trial. For these reasons, all claims are patentable over the art and, accordingly, the rejection of claims 27 to 42 under 35 USC 103(a) as being unpatentable over Englund et al or Cherry should be withdrawn.

It is believed that this application now is in condition for allowance and early and favorable consideration and acceptance is respectfully requested.

Respectfully submitted,

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